

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON TALCUM
POWDER PRODUCTS MARKETING,
SALES PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-
2738-FLW-LHG**

MDL No. 2738

***THIS DOCUMENT RELATES TO ALL
CASES***

**ORAL ARGUMENT
REQUESTED**

**THE PLAINTIFFS' STEERING COMMITTEE'S MOTION AND NOTICE
OF MOTION OBJECTING TO SPECIAL MASTER'S LETTER OPINION
RELATED TO DEFENDANTS' DEMAND FOR PRODUCTION OF
CERTAIN PORTIONS OF THE LABORATORY NOTEBOOKS OF DR.
GHASSAN M. SAED**

PLEASE TAKE NOTICE, that the Plaintiffs' Steering Committee ("PSC") hereby moves the Court to reverse the April 26, 2019 Letter Order of the Special Master and to order that the confidential dipeptide research of a J&J competitor, Temple Therapeutics BV, contained in Dr. Saed's lab notebooks should be deemed as non-discoverable confidential, proprietary trade secrets.

The PSC relies on the attached *Memorandum of Law* with attached Exhibits.

Respectfully submitted,

/s/ Michelle A. Parfitt

Michelle A. Parfitt

ASHCRAFT & GEREL, LLP
1825 K Street, NW, Suite 700
Washington, DC 20006
Tel: 202-783-6400
Fax: 202-416-6392
mparfitt@ashcraftlaw.com

/s/ P. Leigh O'Dell

P. Leigh O'Dell
BEASLEY, ALLEN, CROW, METHVIN,
PORTIS & MILES, P.C.
218 Commerce Street
Montgomery, AL 36104
Tel: 334-269-2343
Fax: 334-954-7555
Leigh.odell@beasleyallen.com
Plaintiffs' Co-Lead Counsel

/s/ Christopher M. Placitella

Christopher M. Placitella
COHEN, PLACITELLA & ROTH, P.C.
127 Maple Avenue
Red Bank, NJ 07701
Tel: 732-747-9003
Fax: 732-747-9004
cplacitella@cprlaw.com

Plaintiffs' Liaison Counsel

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LAW IN SUPPORT OF ITS OBJECTION TO SPECIAL MASTER'S
LETTER OPINION RELATED TO DEFENDANTS' DEMAND FOR
PRODUCTION OF CERTAIN PORTIONS OF THE LABORATORY
NOTEBOOKS OF DR. GHASSAN M. SAED**

I. INTRODUCTION AND BACKGROUND

A. Summary Of Work Performed By Dr. Ghassan M. Saed

This discovery dispute arises from a demand by Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc. (collectively "J&J" or "Defendants") for the production of certain portions of laboratory notebooks of the Plaintiffs' Steering Committee ("PSC") expert, Dr. Ghassan M. Saed.

As set forth below, this discovery dispute involves J&J's relentless effort to force Dr. Saed to breach a confidentiality agreement with one of J&J's competitors, Temple Therapeutics, BV, so that J&J can get its hands on highly confidential and

proprietary competitive information from that competitor. This Court should not countenance such an effort.

Dr. Saed is an Associate Professor of Gynecologic Oncology with tenure at Wayne State University in Detroit, Michigan, where he is the Director of Ovarian Cancer Biology Research. He is also a faculty member in the Departments of Obstetrics & Gynecology, Cell Biology, and Anatomy & Physiology at Wayne State School of Medicine, and a Member of the Karmanos Cancer Institute, Molecular Biology and Genetics Program.

Dr. Saed's laboratory investigates the role of oxidative stress in the pathogenesis of ovarian cancer. His research in ovarian cancer has resulted in the identification of biomarkers for assessing the progression and metastasis of ovarian cancer. Dr. Saed has been the recipient of national and international grants and contracts from many prestigious organizations¹ for his work related to ovarian cancer and he has been an author on over 130 original studies published in peer-reviewed journals, with additional review articles and book chapters. He recently published and review article in the journal, Gynecologic Oncology titled, "*Updates of the role of oxidative stress in the Pathogenesis of Ovarian Cancer: Oxidative Stress*", summarizing his research in this area.

¹ American Association of Cancer Research (AACR); NIH/NICHD; United States Department of Defense; the Ovarian Cancer Research Fund Alliance, and other ovarian cancer research foundations.

Dr. Saed was hired by Temple Therapeutics BV, a pharmaceutical company to perform research regarding dipeptide related to the development of an adhesion prevention drug.² In connection with this highly confidential work, Dr. Saed and Temple Therapeutics BV, executed a “Mutual Confidentiality and Non-Disclosure Agreement” on January 3, 2017.³ J&J is in direct competition with Temple Therapeutics, BV in the area of adhesion prevention, as manufacturers of the GYNECARE INTERCEED® Absorbable Adhesion Barrier.⁴

On November 16, 2018, Dr. Saed submitted an expert report on behalf of the PSC wherein he opined that Defendants’ talcum powder products elicit an inflammatory response in normal ovarian and tubal cells and in ovarian cancer cells that can result in the development and progression of ovarian cancer.⁵ He further opined that the pro-carcinogenic process involves oxidative stress, alteration of the redox environment by increasing oxidant enzymes and decreasing anti-oxidant enzymes, promotion of cell proliferation, inhibition of apoptosis, and induction of

² <http://www.templerx.com/>.

³ The Mutual Confidentiality and Non-Disclosure agreement between Dr. Saed and Temple Therapeutics BV can be made available to the Court for *in camera* inspection upon request.

⁴ <https://www.jnjmedicaldevices.com/en-US/product/gynecare-interceed-absorbable-adhesion-barrier>.

⁵ References to the November 16, 2018 Rule 26 Expert Report of Dr. Ghassan M Saed are referred to herein as the “Saed Report.”

specific genetic mutations. Dr. Saed concluded that exposure to Defendants' talcum powder products result in inflation of CA-125, a clinically relevant biomarker for ovarian cancer, and that Defendants' talcum powder products cause ovarian cancer.⁶ Dr. Saed's work involves research to determine whether or not there was a molecular basis for the observed association between talcum powder and ovarian cancer. If a biological effect was demonstrated, a further objective of Dr. Saed's work was to define the mechanism in detail, if possible.

Issues relating to the pathogenesis of ovarian cancer and the relationship of inflammation and other pathological conditions in the female reproductive system as well as cancer have been the focus of Dr. Saed's laboratory for many years before his involvement in this litigation. The methodology employed by Dr. Saed is outlined in full detail in the Saed Report, as are the statistical analyses he utilized and his research findings. The experiments performed by Dr. Saed were recorded in two laboratory notebooks.

B. Disputes Related To Dr. Saed's Laboratory Notebooks

Prior to the January 23, 2019 deposition of Dr. Saed, Defendants served a *Notice of Deposition & Duces Tecum*, wherein Defendants sought "[c]opies of all laboratory notebook pages corresponding to the research referred to in pages 13-21 of the [Saed Report]." By Order dated December 27, 2018, Special Master Pisano

⁶ Dr. Saed's full opinions are set forth in the Saed Report.

ordered that the “PSC shall produce Dr. Saed’s laboratory notebooks” and furthermore that “[a]ll parties shall produce all laboratory notebooks and any other technical material for an expert who has done scientific testing.”⁷ After a request for clarification, Special Master Pisano made clear that “the experts’ materials that are subject to my order are those materials which relate to the report being considered.”⁸

On January 14, 2019, the PSC produced copies of Dr. Saed’s laboratory notebooks relevant to Defendants’ request. Further, on the day of his deposition, Dr. Saed brought with him the two laboratory notebooks that documented the experiments he had performed relevant to his report.⁹ During the 7-hours of questioning Defendants inquired as to the content of Dr. Saed’s notebooks, including about the various sections of the laboratory notebooks. In fact, in its January 25, 2019 letter to Special Master Pisano wherein Defendants sought the production of additional documents and a continuance of Dr. Saed’s deposition, Defendants’

⁷ See 12/27/18 CMO at ¶¶ 1, 3, attached hereto as Exhibit A.

⁸ See 12/27/18 e-mail from Special Master Pisano to P. Leigh O’Dell, attached hereto as Exhibit B.

⁹ It is against university lab policy to leave laboratory notebooks unattended with a third party and it is for this reason that Dr. Saed brought the laboratory notebooks with him to the deposition.

counsel acknowledged that “a significant amount of time [was] expended simply understanding the distinctions between the lab books.”¹⁰

On February 5, 2019 a continuation of Dr. Saed’s deposition was ordered, Special Master Pisano again confirmed that “Defendants requested production of Dr. Saed’s laboratory notebooks and other documents relating to specific conclusions that he reached and the basis for those conclusions.”¹¹ Dr. Saed was deposed for an additional 3-½ hours on February 14, 2019 and, for a second time, made his laboratory notebooks available to Defendants.

At the February 14, 2019 deposition, Defendants requested that Dr. Saed make the laboratory notebooks available for scanning by a copying service. Dr. Saed accommodated Defendants’ request and allowed all portions of the talcum powder-related research to be copied. However, Dr. Saed did not allow a non-talcum powder section of one of the laboratory notebooks to be copied because it was research conducted from a project commissioned and funded by Temple Therapeutics BV

¹⁰ See 1/25/19 letter from Susan M. Sharko to Hon. Joel A. Pisano at 6, attached hereto as Exhibit C.

¹¹ See 2/5/19 CMO at 1, attached hereto as Exhibit D.

wholly unrelated to this litigation.¹² As Dr. Saed testified, the project involved “looking at the effect of a dipeptide on adhesion markers.”¹³

By letter dated April 12, 2019, Defendants’ raised issue with the fact that Dr. Saed had not permitted the copying of the dipeptide research, arguing that they wanted copies of the entirety of both lab notebooks.¹⁴ By letter dated April 17, 2019, the PSC responded, again pointing-out that the dipeptide research was unrelated and not relevant to the work performed and opinions expressed by Dr. Saed in the present litigation.¹⁵ The PSC further pointed out that the information is confidential and was done as part of an FDA pre-market approval for a pharmaceutical product.¹⁶

On April 19, 2019, Special Master Pisano sent an e-mail seeking clarification on specific points. In particular, he inquired: (a) whether the studies were co-mingled; (b) whether the parties had discussed the copying of the entire lab notebooks; (c) whether the notes on the dipeptide research were disclosed during the

¹² See January 23, 2019 Deposition of Ghassan Saed, Ph.D. (“Saed. Dep.”) at 84:3-85:10. Relevant excerpts from the Saed Dep. are attached here as Exhibit E.

¹³ *Id.* at 56:13-57:5 (hereinafter “dipeptide research”). Dr. Saed further testified that it is customary for the lab to use one lab notebook for multiple projects provided there is available room. *Id.*

¹⁴ See 4/12/19 letter to Hon. Joel A. Pisano from Susan M. Sharko, attached hereto as Exhibit F.

¹⁵ See 4/17/19 letter to Hon. Joel A. Pisano from P. Leigh O’Dell, attached hereto as Exhibit G.

¹⁶ *Id.*

deposition; (d) whether members of the PSC had reviewed the notes; and (e) whether the dipeptide research can be disclosed subject to the Discovery Confidentiality Order. Defendants and the PSC responded to Special Master Pisano's inquiries by letters dated April 22, 2019, and April 23, 2019, respectively.¹⁷

On April 26, 2019, Special Master Pisano entered an Order requiring the entire laboratory notebook be copied and produced to defense counsel.¹⁸ He did so despite no finding that the information ordered to be produced is relevant to the litigation, actually noting to the contrary that "the unproduced laboratory notebook pages on *an unrelated project* may be of no use to counsel in this matter."¹⁹ Special Master Pisano's finding were also based upon improper and inaccurate findings of fact, whereby he improperly stated that Dr. Saed "was shown to be less than forthcoming in his production of laboratory work materials" despite his lab notebooks being made available to counsel for nearly 15 hours during deposition. He held that Dr. Saed had "altered laboratory notebook entries, he combined, incorporated, or commingled

¹⁷ See April 22, 2019 letter to Hon. Joel A. Pisano from Susan M. Sharko, attached hereto as Exhibit H; April 23, 2019 letter to Hon. Joel A. Pisano from P. Leigh O'Dell, attached hereto as Exhibit I.

¹⁸ See April 26, 2019 Letter Order at 3 (hereinafter "Letter Order"), attached hereto as Exhibit J.

¹⁹ *Id.* at 2 (emphasis added). Special Master Pisano reiterated the lack of relevance of the dipeptide research by referring to it as "unrelated laboratory notes" on multiple occasions.

notes from different studies in the same notebook.”²⁰ However, Special Master Pisano made this finding without even seeing the very lab notebooks about which he ruled. Instead, he relied only upon the self-serving statements contained in letters from defense counsel whose intent was to tarnish the record while seeking to obtain information that was different from the discovery that was at issue in the dispute and had been ordered to be produced. In other words, the discovery dispute morphed into a quest by Defendants to obtain confidential and proprietary information from one of its competitors that was beyond the scope of the original dispute and beyond the permissible scope of discovery in the case.

Special Master Pisano’s decision also called into question the ability to claim privacy considerations related to the dipeptide research because Special Master Pisano believed that Dr. Saed never asserted a privilege related to the research. However, Dr. Saed did testify that the research was unrelated to the present matter and, after so stating, he was asked no further questions about the research that would have warranted such a claim. Special Master Pisano incorrectly found that he did “not know, nor do I now find, whether the unrelated laboratory notes are subject to any privilege, as no such argument has been made.”²¹ However, the PSC, in fact, argued privilege and confidentiality on multiple occasions after Defendants first

²⁰ *Id.* at 3.

²¹ *Id.*

raised the issue of producing the dipeptide research on April 12, 2019. *See* Ex. G (4/17/19 letter stating that “[t]he study design and results are proprietary and confidential.”); *see also* Ex. I (4/23/19 letter “The lab notebooks were reviewed to identify and ensure that all talc-related data and information was disclosed in compliance with Your Honor’s order... [N]either I nor lawyers on behalf of the PSC reviewed the data in detail because it was proprietary, confidential, and not relevant to the Talc MDL litigation.”

The decision of Special Master Pisano to require the production of the confidential and proprietary dipeptide research of one of J&J’s competitors is erroneous both as to his findings of fact and conclusions of law.

II. ARGUMENT

A. STANDARD OF REVIEW

Federal Rule of Civil Procedure 53 sets forth the standard this Court must apply when reviewing a report and recommendation of a Special Master. *See* Fed. R. Civ. P. 53(f)(3)-(5). With respect to the Special Master’s decisions, the Court “may adopt or affirm, modify, wholly or partly reject or reverse, or resubmit to the master with instructions.” Fed. R. Civ. P. 53(f)(1). Rule 53(f) further provides that “[t]he court must decide *de novo* all objections to conclusions of law made or recommended by a master.” Fed. R. Civ. P. 53(f)(4). Similarly, all objections to the

master's findings of fact, unless the parties stipulate otherwise, are reviewed *de novo*. See Fed. R. Civ. P. 53(f)(3).

With regard to the present issue there has been no stipulation regarding the standard of review and the Special Master's findings of fact and conclusions of law should therefore be reviewed *de novo* pursuant to Fed. R. Civ. P. 53(f)(3)-(4). For the reasons set forth below, this Court should conclude that the Special Master erred and made incorrect findings of fact by: (1) finding that Dr. Saed had improperly altered laboratory notebook entries, and combined, incorporated, or commingled notes from different studies in the same notebook; and (2) finding that the claims of privilege and confidentiality had not been asserted in regard to the dipeptide research. Special Master Pisano also erred as a matter of law by: (1) ruling that the dipeptide research had to be produced despite the absence of any finding that the research is relevant or required to be produced pursuant to Fed. R. Civ. P. 26; and (2) by failing to rule that the information was privileged and confidential. The decisions of the Special Master should be reversed.

B. SPECIAL MASTER PISANO MADE ERRONEOUS FINDINGS OF FACT

1. The Special Master improperly found that Dr. Saed altered and comingled his laboratory notebooks

The Special Master was incorrect in finding that Dr. Saed “was shown to be less than forthcoming in his production of laboratory work materials” and that he

had “altered laboratory notebook entries, [] combined, incorporated, or comingled notes from different studies.”²² The findings are based only upon a review of Dr. Saed’s deposition transcript and the self-serving statements put forward by defense counsel. During his deposition, Dr. Saed made clear that the dipeptide research was not combined, incorporated or comingled with the relevant talc research. When questioned, Dr. Saed clearly testified that the studies were separate and that the dipeptide study was in the first part of the notebook. *See* Saed Dep. at 57:4-5 (“The first part is for the different study. This part where we started the actual work with talc.”); 84:3-10:

Q. Then on the other lab notebook that contained – that was on Exhibit 2. Exhibit 3 on the outside is something called Temple 1. What does that mean?

A. That’s a project that we did for Temple Pharmaceutical in our lab.

Q. That’s a project that’s – that’s the project that’s in the first part of the lab notebook?

A. Correct.

There is no other information in the record to indicate that the dipeptide research was at all combined, incorporated or comingled with information relevant to the Talc MDL litigation.

²² *See* Letter Order at 3.

Nor is there evidence to support a finding of fact that Dr. Saed was less than forthcoming about his laboratory notebook entries. Dr. Saed testified regarding the work he performed, including the laboratory notebooks, for over 10-hours over a 2-day period of time. He answered all questions presented to him regarding his work and the notebooks. Not only were counsel provided with copies of the lab notebook pages relevant to the Talc MDL, but Defendants were provided with the actual lab notebooks during the 2 days of deposition.

Most telling, the Special Master made the findings of fact regarding the lab notebooks without ever having seen the actual lab notebooks or copies of the lab notebook pages. In fact, the Special Master even ignored the Defendants' own suggestion that, as an alternative, "it would be appropriate for Your Honor to review the materials in camera and assess what other protections might be appropriate and necessary."²³ To find that information in the lab notebooks is "combined, incorporated, or comingled" **without even seeing the actual notebooks** represents a clear error. The Special Master was incorrect in finding that the dipeptide research conducted by Dr. Saed was combined, incorporated or comingled with relevant talc research. The Special Master was also incorrect that Dr. Saed was less than forthcoming about his lab notebook entries. As a result, the findings of the Special Master should be reversed.

²³ See April 22, 2019 letter.

2. The Special Master improperly found that the information at issue was not claimed to be proprietary

The finding by the Special Master that the PSC failed to assert that the dipeptide research was proprietary is in error. As outlined above and in the record that was before the Special Master, the dipeptide research for a competitor of J&J was not addressed at any time prior to Defendants' April 12, 2019 letter requesting that the research be copied and produced.²⁴ After Dr. Saed identified the dipeptide research in the lab notebook as being the part of a different study it was never again discussed. As indicated by the PSC, "the lab notebooks were reviewed to identify and ensure that all talc-related data and information was disclosed in compliance with Your Honor's order. Part of that process included the cursory review of the non-talc related study to determine when the documentation for the study ended in the notebook." April 23, 2019 letter at 2.

In response to Defendants' April 12, 2019 letter, the PSC, on multiple occasions, asserted that the dipeptide research was proprietary. *See* April 17, 2019 letter at 2 "The study design and results are proprietary and confidential."); April 23, 2019 letter at 2 ("However, neither I nor lawyers on behalf of the PSC reviewed the

²⁴ It was also incorrect for the Special Master to find that "Defendants asked questions of Dr. Saed during the deposition relating to those sections of the notebook." Letter Order at 2. The only questions asked about the dipeptide research were for identification of the section that contained the research. No substantive questions were asked.

data in detail because it was proprietary.”). It was not until Defendants sought disclosure of the dipeptide research of one of J&J’s competitors that the PSC had any reason or basis for having to assert that the research was proprietary and a finding that the PSC failed to raise the issue is contrary to the record. As set forth above, J&J is in direct competition with Temple Therapeutics, BV the pharmaceutical company that Dr. Saed is working with to develop an adhesion prevention treatment. Dr. Saed has a confidentiality agreement with Temple Therapeutics preventing him from providing the confidential information that J&J seeks about a competitor’s drug. J&J is clearly attempting to gain an unfair competitive advantage by forcing Dr. Saed to breach his confidentiality agreement.

C. SPECIAL MASTER PISANO MADE ERRONEOUS CONCLUSIONS OF LAW

1. It was an error of law for the Special Master to hold that the materials at issue are relevant to the Talc MDL litigation

It was a clear error of law for the Special Master to hold that the materials at issue are relevant to the Talc MDL litigation and should be produced. As noted in the Letter Order, the Special Master was clear that his prior orders required the “production of materials that relate to the report being considered, and not all research from an expert’s laboratory.”²⁵ Further, pursuant to Rule 26(a)(2), an expert is not required to produce materials and information that are not related to the

²⁵ See Letter Order at 1. See also 12/27/18 e-mail from Special Master.

opinions be offered. Instead, an expert witness is required to produce “the facts or data considered by the witness in forming them.” Fed. R. Civ. P. 26(a)(2).

Dr. Saed did not at all consider the facts or data contained in the dipeptide research in forming the opinions he has expressed in this litigation. There is nothing in the record that permits a finding otherwise. In fact, Defendants do not even argue that the material was considered by Dr. Saed or that it is relevant to the litigation. Most telling, the Special Master several times acknowledged that the dipeptide research was “irrelevant,” and “unrelated laboratory notes.”²⁶ Neither Rule 26(a)(2) nor any of the Federal Rules require the production of information that is not relevant to the litigation. As such, the Special Master’s order that the confidential and proprietary dipeptide research belonging to one of J&J’s competitors be produced is a clear error of law and should be reversed.

2. It was an error of law for the Special Master to hold that the materials at issue are not confidential and privileged

Rule 26(c) of the Federal Rules of Civil Procedure are designed to protect parties from the disclosure of trade secrets. *See Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1122 (3d Cir. 1986). This litigation is also governed by a Discovery Confidentiality Order. Moreover, Rule 26 applies not only to the parties to a litigation, but also to third parties seeking to protect privileged trade secrets. *See*

²⁶ *See* Letter Order at 2 and 3.

Stanziele v. Career Path Training Corp. (In re Student Finance Corp.), 2006 U.S. Dist. LEXIS 86603, at *33-34 (E.D. Pa. Nov. 29, 2006) (holding that the language of Rule 26(3) is sweeping enough to provide protections to third parties against disclosure). The burden of establishing that a privilege is within the confines of the rules falls upon the proponent of the privilege. *See Caruso v. Coleman Co.*, 1995 U.S. Dist. LEXIS 8419, at *1 (E.D. Pa. June 22, 1995). *See also In re Grand Jury Investigation*, 918 F.2d 374, 385 fn. 15 (3d Cir. 1990) (discussing Third Circuit rule that the party invoking privilege has burden of proving applicability).

The PSC has put for the requisite facts to establish that the dipeptide research at issue involves privileged trade secrets. Dr. Saed testified that the research involved “looking at the effect of a dipeptide on adhesion markers.”²⁷ This research was done on behalf of a third- party, Temple Therapeutics, BV. The PSC further asserted facts with regard to the dipeptide research further establishing that the research is a trade secret. *See* 4/17/18 letter (the lab notebook “contains documentation and data from a research project commissioned and funded by Temple Pharmaceuticals... as part of the FDA pre-market approval process for a pharmaceutical drug.”). *See also* 4/223/18 letter at 2 (stating that the PSC only did a cursory review to determine where the study ended because the research was “proprietary, confidential, and not relevant to the Talc MDL litigation.”). Given the proprietary nature of the dipeptide

²⁷ Saed Dep. at 56:13-57:4; 84:6-7.

research it was an error of law for the Special Master to order that the research be turned over to counsel.²⁸

III. CONCLUSION

For the foregoing reasons the Court should order that the April 26, 2019 Letter Order should be reversed, and the confidential proprietary dipeptide research contained in Dr. Saed's lab notebooks belonging to a J&J competitor, Temple Therapeutics, BV should be deemed proprietary trade secrets. Alternatively, the documents should be subject to an *in camera* review so that the Court or the Special Master can determine the relevance of the documents, if at all. Given the significances of the issues presented and important to the PSC, Dr. Saed and Temple Therapeutics, BV, oral argument is requested.

Respectfully submitted,

/s/ Michelle A. Parfitt
Michelle A. Parfitt
ASHCRAFT & GEREL, LLP
1825 K Street, NW, Suite 700
Washington, DC 20006
Tel: 202-783-6400
Fax: 202-416-6392
mparfitt@ashcraftlaw.com

/s/ P. Leigh O'Dell
P. Leigh O'Dell
BEASLEY, ALLEN, CROW, METHVIN,

²⁸ The sensitivity of the issue is heightened by the fact that the dipeptide research involves a product J&J is actively involved in the research in competition with Temple Therapeutics BV.

PORTIS & MILES, P.C.
218 Commerce Street
Montgomery, AL 36104
Tel: 334-269-2343
Fax: 334-954-7555
Leigh.odell@beasleyallen.com
Plaintiffs' Co-Lead Counsel

/s/ Christopher M. Placitella
Christopher M. Placitella
COHEN, PLACITELLA & ROTH, P.C.
127 Maple Avenue
Red Bank, NJ 07701
Tel: 732-747-9003
Fax: 732-747-9004
cplacitella@cprlaw.com
Plaintiffs' Liaison Counsel